

Application No.: 09/369,410

Case No.: 54982US002

Remarks

With this paper, claim 21, 29 and 30 have been amended, and claims 27 and 28 have been canceled. Claims 21-26 and 29-38 are presented for examination. Support for the amendment to claim 21 is found, for example in canceled claim 27 and 28 which had been submitted with the Preliminary Amendment of June 2, 2004. The amendments to claims 29 and 30 are merely to correct their dependencies in light of the cancellation of claims 27 and 28.

In the recent Office Action, claims 21-34 and 36-38 were rejected under 35 U.S.C. §103(a) as unpatentable over Augurt (US 5,200,247) in view of Sandstrom (US 5,631,171). Augurt is said to teach a chemical indicator test sheet comprised of a flat surface capable of reflecting energy and having a sterilizing agent sensitive ink. The Office acknowledges that Augurt does not teach specific elements of a reflectometer but as suggesting that the sheet be analyzed with a reflectometer. Sandstrom is said to teach an instrument containing an illumination source, a detector, positioning means, a controller and a processing means. The processing means (a computer) is said to include memory means and microprocessing capability, and the illumination source is said to be capable of providing multiple wavelengths of light and providing light at the angles required. The Office Action asserts that one of ordinary skill in the art would combine the apparatus of Sandstrom with the indicator of Augurt to obtain the invention claimed in the present application.

Applicant respectfully traverses the rejection.

As is set forth in the above claims, the present invention provides a system comprising:

- (A) A chemical indicator comprising a substantially flat surface capable of reflecting energy therefrom, and a sterilizing agent sensitive ink associated with the surface, the ink providing a first indicating state prior to being exposed to the sterilization process, and a second indicating state after being exposed to at least a portion of the sterilization process, the first and the second indicating states being distinguished one from the other by color of the surface; and

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- (C) An apparatus for reading the chemical indicator, the apparatus comprising;
- (i) an illumination source configured and positioned to provide energy and to direct the energy toward the substantially flat surface of the chemical indicator;
 - (ii) a detector configured to collect energy reflected from the substantially flat surface and to provide a signal characteristic of the wavelength of the energy reflected from the substantially flat surface;
 - (iii) positioning means for positioning the substantially flat surface of the chemical indicator relative to the illumination source and the detector;
 - (iv) a controller controllably connected to the detector and the illumination source; and
 - (v) processing means for processing the signal from the detector to distinguish the first and second states and for determining whether the chemical indicator is in the first state or the second state, the processing means including nonvolatile memory that includes reference data comprising data generated from sterilization indicators that have been exposed to varying degrees of a sterilization process. (See amended claim 21).

Augurt describes a test pack for the detection of common sterilization flaws. The test pack described by Augurt includes a test sheet with areas of ink thereon. The ink is adapted to change color from white to black upon exposure to steam. A black color indicates exposure to steam sterilization while and incomplete change to black (e.g., white or brown) is indicative of an insufficiency of exposure to steam. (See col, 2, lines 43-65). Augurt mentions that his test sheet is intended to be viewed visually for an evaluation of a color change. While Augurt discloses the use of a reflectometer as a means for measuring a color change, the color change measured is from white to black. (See col. 10, lines 6-24). The reflectometer used by Augurt is obviously measuring reflected light intensity and is not directly measuring changes in wavelength. Moreover, nothing in

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the Augurt teaching includes a mention that the reflectometer evaluation indicates that it included a detector configured to collect reflected energy to provide a signal characteristic of the wavelength of the energy reflected from surface. Moreover, nothing within Augurt suggests that the reflectometer would or should be equipped with processing means that includes nonvolatile memory for reference data generated from sterilization indicators that have been exposed to varying degrees of a sterilization process.

Sandstrom, cited in the Office Action as a secondary reference, relies on the polarization characteristics of the light reflected by a sample, not the wavelength, to determine the properties of thickness or refractive index. Applicant has noted no teaching to detect reflected energy in order to provide a signal that is characteristic of the wavelength (or color) of the reflected light. Neither Augurt nor Sandstrom teach or suggest the measurement of reflected light to determine true color changes (by wavelength) or to provide processing means for processing a signal from the detector to distinguish the first and second states (or first and second colors) and for determining whether the chemical indicator is in the first state or the second state. Nothing in Sandstrom or Augurt teach or suggest that the processing means include nonvolatile memory with reference data generated from sterilization indicators that have been exposed to varying degrees of a sterilization process. With the inclusion of non-volatile memory and reference data, the present invention provides a system that affords the user the ability to: a) acquire, store and use sterilization monitoring information quickly and cost effectively without the delay, cost and inaccuracy associated with prior art sterilization indicators, b) reduce sterile products inventory hold time, c) increase the accuracy of information storage and provide higher levels of accuracy in data management, d) possess a unified, integrated sterility assurance and inventory management system, e) minimize the potential for human error in a system for monitoring the sterilization of articles, and f) customize sterilization assurance information for site specific needs. Such a system is neither suggested nor taught by the cited art.

For the foregoing reasons, Applicant respectfully requests the reconsideration and the withdrawal of the rejection of claims 21-34 and 36-38 to the extent the rejection is based on the combination of Augurt and Sandstrom.

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Applicant has noted the additional rejection of Applicant's dependant claim 35. In view of the foregoing, it is believed that independent claim 21 is now allowable over the cited art. Therefore, dependent claim 35 should also be allowable in view of its dependency from claim 21.

Applicant has endeavored to address all of the issues raised in the recent final Office Action. It is believed that the application is in condition for allowance, and the allowance of all claims is now requested.

Respectfully submitted,

Date

Sept. 30, 2004

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